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**Before the U.S. EPA's Clean Air Scientific Advisory Committee
on the Review of EPA's second draft Integrated Science Assessment for Ozone**

March 9, 2012

Good morning and thank for the opportunity to present some brief comments on the CASAC review of the draft ISA for ozone.

We recognize the importance of getting the science right and are appreciative of this committee's efforts. We note that these CASAC and public reviews were preceded by a well-attended scientific kickoff workshop in October 2008 as well as additional peer review and author workshops in 2010. This committee provided EPA with 100 pages of technical comments on the first draft ISA and now again with another 100 pages of comments on the second draft document. We believe the Agency can be trusted to carefully consider these comments in preparing a final ISA.

In reviewing the committee's draft letter, I don't see any show stoppers that would require another round of review. The notion of multiple draft criteria documents harkens back to the days before the reform of the CASAC review process. As you recall, these reforms were initiated when extensive delays in the scientific review process caused the criteria documents to get stale, while new scientific findings continued to be published.

I would like to comment briefly on the issue of respiratory symptoms in asthmatic children. The draft comments argue that newer multi-city studies such as Schildcrout, 2006 and O'Conner, 2008 should carry the most weight.

However, there are some unexplored issues with the Schildcrout study, which deserve your consideration. As you may recall, a number of industry groups seized upon this study to argue against the strengthening of the ozone NAAQS in the last review.

In a January 4, 2008 letter to EPA Administrator Steven Johnson, Dr. Jonathan Schildcrout, the lead author of the paper, took issue with the industry claims:

"I searched through the Annapolis Center document, a National Association of Manufacturers letter, and a document titled "Comments on EPA's Revisions to National Ambient Air Quality Standards for Ozone," to examine how the manuscript I wrote was being used to support the claims. My

interpretation of their interpretation is that we conducted a very large study on 990 children and found no evidence to suggest any sort of ambient ozone impact on children with asthma. Because the study was very large and because results were 'inconsistent' with prior studies, the results should cast a large amount of doubt on our knowledge of this topic. My interpretation of the results from the manuscript, and in light of other research on this topic, is different. Indeed we found no evidence to suggest an ambient ozone effect. **While we had studied a total of 990 children in most analyses (of nitrogen dioxide, carbon monoxide, coarse particulate matter and sulphur dioxide), the analyses involving ozone, as described in the manuscript, considered the May through September months. There were far fewer than 990 subjects examined in ozone related analyses. In addition, over the course of the study, an average of approximately 12 subjects were observed per day. Thus, over these warm season months we do not have a large number of children being observed at any point in time.** This is addressed in our discussion. Other large multi-city studies observed far more children at once (e.g., Mortimer et al., 2002). Further, that other studies found "statistically significant" effects while ours did not, does not imply the results are inconsistent. Thorough evaluation of study populations, uncertainty in parameter estimates, precise scientific questions (i.e., the outcome and exposure) etc., are necessary in order to draw such a conclusion.

In an overall way, the size of our study was not as large as was suggested in the above mentioned documents. This manuscript should add to the growing literature on the health effects of ambient ozone and other pollutants, but it is my belief that the research we conducted on ozone, and in light of all of the research that has been conducted on this topic in the past, should not by itself, tip the balance regarding ozone standards in any direction. While I believe it should be considered by the CASAC, I strongly believe that it should not be used as the primary basis for overruling their recommendations.

I write this message because I want to clarify my view on this topic. Additionally, I do not want the results of my manuscript to be misinterpreted."

Indeed the Schildcrout paper cites 12 other studies that showed that ozone has been repeatedly found to harm children with asthma.

Schildcrout et al (2006) itself notes, "A total of 990 children were followed over the course of 22 months; however, **on a given day, the average number of children observed was approximately 12 per city, making season-specific effects difficult to capture. More thorough city-specific analyses may also be appropriate for the analysis of ozone.**

In other words, because of the limited number of children included at any one time, this study may be underpowered to detect any effect of ozone.

The point is that this and other recent studies need to be carefully evaluated to consider study populations, uncertainty in exposure estimates, health endpoints and other factors and placed in the context of forty years of research on the adverse effects of ozone on children with asthma.